



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

2005 5 MAR 1 2005

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Cary A. Levitt, Esq.
Solae, LLC
P.O. Box 88940
St. Louis, Missouri 63188

RE: Qualified Health Claim (Soy Protein Containing Products and a Reduced Risk of
Certain Cancers) (Docket No. 2004Q-0151)

Dear Mr. Levitt:

This letter is to inform you that the Food and Drug Administration (FDA) is reopening to April 11, 2005, the comment period for your qualified health claim petition. The petition, submitted March 1, 2004, requests a qualified health claim for the relationship between soy protein containing products and a reduced risk of certain cancers. FDA has received a few comments on the additional data you submitted. For FDA to be transparent and responsive to all comments received, we have decided to re-open the comment period for 30 days.

Please feel free to contact Dr. Tomoko Shimakawa at 301-436-1450 if you have questions concerning this petition.

Sincerely yours,

Barbara O. Schneeman, Ph.D.
Director
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

CC: Gregory L. Paul, Ph.D., Solae Company, Steven B. Steinborn, Esq. Hogan & Hartson,
L.L.P.

2004Q-0151

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